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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,540	04/15/2005	Stanka Perc	4061-27PUS	1415

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,540	PERC ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-33* is/are pending in the application.

4a) Of the above claim(s) *33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Sheets (3)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 18-33 are currently pending in the application.

Applicant's election without traverse of group I (i.e. pharmaceutical composition) in the reply filed on 02/25/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claim 33 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) for foreign priority based on an application filed in Slovenia on 10/10/2002, which papers have been placed of record in the file.

IDS

The information disclosure statement filed 02/25/08 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it includes search report

citations. Applicant is advised that a search report is not a published document and therefore is not properly listed § 609.05(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-28 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. (EP 0 830 858 A1, already cited by applicant and filed on an IDS 1449) as evidence by Nakajima et al. (U.S. 3,926,817).

Specifically, Morris et al. teaches an oral formulation where the active ingredient olanzapine is subcoated and mixed with acceptable excipients (instant claim 18, see abstract and pg. 2, lines 49). The anhydrous form of olanzapine (see pg. 2, lines 54-55) was found to overcome the undesirable discoloration problems of the prior art and found to be stable due to the subcoating of the active ingredient (see pg. 2, lines 35-37 and line 50). The formulation is preferably in a tablet form (instant claim 32). Morris et al. further teaches that the oral formulation can contain diluents such as lactose, binders such as hydroxypropyl cellulose and microcrystalline cellulose, disintegrants such as crospovidone, and lubricants and glidants such as magnesium stearate (instant claims 18). Morris et al. teaches that the subcoated form II of olanzapine was used (see pg. 7,

Preparation 2, Form II, lines 15-23) and mixed with 232.12 mg (i.e. 71.4% of b component or oligosaccharide), 13 mg (i.e. 4%) hydroxypropyl cellulose and 40 mg (i.e. 12.3% binder) microcrystalline cellulose (i.e. 16.3% polysaccharide or component (c) or binders), 16.25 mg of crospovidone (i.e. 5% disintegrant) and 1.63 mg of magnesium stearate (i.e. 0.5% lubricant and glidant) (see instant claims 18-28; see pg. 8, example 3). Morris et al. also teaches that the coated olanzapine is blended along with the aforementioned excipients and compressed with the appropriate tooling on tablet compression equipment (See pg. 8, lines 35-39). Morris et al. did not teach the inclusion of solvent during compression so this meets the limitation of claim 18.

Nakajima et al. has been provided to demonstrate that magnesium stearate is known in the art to be a glidant as well (see col. 8, claim 7).

With regard to Claim 18 which is/are a product by process claim(s), the product disclosed by the prior art is identical to the claimed product, even though (it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art. When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Accordingly, the teachings of Morris et al. anticipate claims 18-28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-30 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Morris et al. (EP 0 830 858 A1, already cited by applicant and filed on an IDS 1449) as evidence by Nakajima et al. (U.S. 3,926,817).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Morris and Nakajima references are as discussed above and incorporated by reference herein. Morris et al. does not particularly teach 70-90% weight % of 20-30 weight % of cellulose or 0.2-0.4 weight of a glidant.

Morris et al., however, does teach approximately16.3% of cellulose (i.e. hydroxypropyl cellulose and microcrystalline cellulose) or 0.5% of magnesium stearate which is considered to be both a glidant and a lubricant. Consequently, it is well within the purview of the skill of the artisan at the time of the invention to adjust the concentration and range of the excipients of the oral formulation during the course of routine experimentation so as to obtain the desirable type of tablet.

While the exact percentage of the excipients are not disclosed by Morris et al., it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to vary the percentages of the glidant and cellulose components for improving the stability of the tablet formulation. Given that Morris et al. teaches an oral formulation of olanzapine with additional excipients such a glidants, binders, disintegrants, lubricants and diluents, one of ordinary skill would have been motivated to vary the components of the excipients of the oral formulation of Morris et al. with the reasonable expectation of providing an improved stable oral formulation of olanzapine.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

04/14/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617